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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,731	04/30/2001	George Jackowski	2132.029	3804
21917	7590	10/29/2003		
			EXAMINER	
			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/845,731	JACKOWSKI ET AL.
	Examiner	Art Unit
	Carolyn L Smith	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 25 August 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1 and 36-43 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1 and 41-43 is/are allowed.

6) Claim(s) 36-40 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 30 May 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicant's amendments and remarks, filed 8/25/2003, are acknowledged. Claim 1 is in allowable form so that claims 36-43 are hereby rejoined.

Applicant's arguments, filed 8/25/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The corrected drawings were received on 5/30/2003. These drawings have been accepted by the draftsman.

Claims 1 and 36-43 are herein under examination.

### ***Claims Rejected Under 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

## **LACK OF WRITTEN DESCRIPTION**

Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

In claim 36, line 6, the phrase “effective to maximize” in connection with the elucidation of discernible peptide fragments is not supported by the specification, drawings, or claims as originally filed. There does not appear to be support for the word “and” (line 15) in rejoined claim 36. (It is noted that if the word “and” was amended to the word “or”, it would not be NEW MATTER.) In claim 38, line 3, the word “cerebrospinal” does not have written support. Written basis is provided for “spinal” (page 32, line 3), but not for “cerebrospinal” as stated in claim 38. Because the introduction of “effective to maximize” (claim 36), “and” (claim 36, line 15), and “cerebrospinal” (claim 38) lacks written basis for rejoined claims 36 and 38, it is considered NEW MATTER. Claims 37, 39, and 40 are also rejected due to their dependency from claim 36. This rejection is necessitated by amendment.

#### LACK OF SCOPE OF ENABLEMENT

Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a portion of a method for diagnosing myocardial infarction, congestive heart failure and intracerebral hemorrhage, does not reasonably provide enablement for a complete method of such diagnosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 36 lacks a purification step and any necessary sample preparation step(s) to get the sample in a form that can be analyzed by mass spectrometry between steps (a) and (b). A sample from a patient as cited in claims 37 and 38, for example, seem quite complex regarding peptide content as well as proteins in general. It does not appear that one skilled in the art can

perform step (b) reasonably in claim 36 merely with a generic “effective to maximize elucidation of discernible peptide fragments” without some type of purification of such fragments out of a myriad of complex proteins, peptide fragments, and other biomolecules in the samples such as in claims 37 and 38. Claims 37-40 are also rejected due to their direct dependence from claim 36. This rejection is necessitated by amendment.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are purification and any other necessary sample preparation steps in between steps (a) and (b) of claim 36 which are required to get the sample in a form that can be analyzed by mass spectrometry later in step (b). A sample from a patient as cited in claims 37 and 38, for example, seem quite complex regarding peptide content as well as proteins in general. It is unclear how one can perform step (b) reasonably in claim 36 merely with a generic “effective to maximize elucidation of discernible peptide fragments without some type of purification of such fragments out of a myriad of complex proteins, peptide fragments, and other

biomolecules in the samples such as in claims 37 and 38. Claims 37-40 are also rejected due to their direct dependence from claim 36. This rejection is necessitated by amendment.

***Conclusion***

Claims 1 and 41-43 are allowed.

Claims 36-40 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 28, 2003

*Carolyn H. Marschel*  
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